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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR         | ATTORNEY DOCKET NO.      | CONFIRMATION NO.       |
|--|-------------|------------------------------|--------------------------|------------------------|
| 09/701,583   | 02/05/2001  | Karl-Hermann Schlingensiepen | P66141US0                | 7033                   |
| 136  | 7590        | 08/30/2007                   |                          |                        |
| JACOBSON HOLMAN PLLC<br>400 SEVENTH STREET N.W.<br>SUITE 600<br>WASHINGTON, DC 20004 |             |                              | EXAMINER<br>ZARA, JANE J |                        |
|  |             |                              | ART UNIT<br>1635         | PAPER NUMBER           |
|  |             |                              | MAIL DATE<br>08/30/2007  | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Advisory Action**  
**Before the Filing of an Appeal Brief**

Application No.

09/701,583

Applicant(s)

SCHLINGENSIEPEN ET AL.

Examiner

Jane Zara

Art Unit

1635

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 07 August 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☒ The Notice of Appeal was filed on 07 August 2007. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 1,2 and 7-11.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
Please see attached.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

*J. Zara*  
TC1600  
JANE ZARA, PH.D.  
PRIMARY EXAMINER

Attachment

Claims 1, 2, 7-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record set forth in the Office action mailed 12-6-06.

Applicant's arguments filed 8-7-07 have been fully considered but they are not persuasive. Applicant argues that written description has been satisfied because the claims are now amended to SEQ ID Nos. 7, 9 and 14. Contrary to Applicant's assertions, the amendments to claims 1, 2, 7-9 do not change the written description requirements for the additional agents claimed, drawn to the very broad genus comprising at least one stimulator positively effecting an immune response, comprising an inhibitor of the effect of a substance that negatively effects an immune response, which stimulator enhances the synthesis and/or function of factors selected from GM-CSF, SCF, CSF, IFN, FLT-3-ligand, monocyte chemotactic proteins, IL-2, IL-4, IL-12 and/or IL-18, a virus, viral antigen, tumor or pathogenic antigen, or organ specific antigens expressed in affected organs but not essential for the organism or fusion of dendritic and tumor cells.

The specification and claims do not indicate or adequately describe elements essential to the genera claimed, which genera include the negative effectors and stimulators claimed. The specification and claims do not indicate the distinguishing attributes concisely shared by the members of the genera comprising these negative effectors or stimulators. The disclosure does not clarify the common attributes that are encompassed by inhibitors of the synthesis or function of negative effectors of the

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immune system. The disclosure does not clarify the common attributes encompassed by stimulators that enhance the synthesis and/or function of GM-CSF, SCF, CSF, IFN, FLT-3-ligand, monocyte chemotactic proteins, IL-2, IL-4, IL-12 and/or IL-18, a virus, viral antigen, tumor or pathogenic antigen, or organ specific antigens expressed in affected organs but not essential for the organism or fusion of dendritic and tumor cells.

Furthermore, the disclosure does not adequately describe the attributes or concise characteristics encompassed by the genera comprising antigens, tumor or pathogenic antigens, or organ specific antigens expressed in affected organs but not essential for the organism or fusion of dendritic and tumor cells. Thus the scope of the claims includes numerous structural variants and the genera are highly variant because a significant number of structural differences between members of a given genus is permitted. Concise structural features that could distinguish structures or compounds within a genus from others are missing from the disclosure and the claims.

Claims 1, 2, 7, 8, 10 and 11 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 12-15 of copending Application No. 10/984,919 for the reasons of record set forth in the Office action mailed 12-6-06.

Both sets of claims are drawn to pharmaceutical compositions comprising at least one inhibitor of an immune suppressor (e.g. antisense targeting and inhibiting the expression of TGF-beta or its receptors) and one immune stimulator (see accompanying sequence alignment data of SEQ ID NO: 528 of 10/984,919 and SEQ ID NO. 7 of the instant application: They are the same oligonucleotide).

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Zara whose telephone number is (571) 272-0765. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz, can be reached on (571) 272-0763. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**Jane Zara**  
**8-27-07**

*JZ*  
TC1600  
JANE ZARA, PH.D.  
PRIMARY EXAMINER